

BIOETHICS EXCHANGE

A NEWSLETTER FOR THE JOHNS HOPKINS-FOGARTY AFRICAN BIOETHICS TRAINING PROGRAM

VOLUME 1, ISSUE 2
MARCH 2005

FROM THE DIRECTOR

Welcome to the 2nd issue of *The Bioethics Exchange*. We are thrilled at the response to the 1st newsletter. We would like this to continue to be a resource for the larger community of scholars and practitioners interested in research ethics, bioethics, and Africa, and not simply for our own trainees.

Part of the purpose of this newsletter is to facilitate exchange among our own alumni trainees and also between our trainees and others working in this area. In that spirit, a request that emerged from a networking meeting in October 2004 of all the Fogarty International Center bioethics training programs was for the creation of a database of all African trainees who have received Fogarty sponsored bioethics training. This database lists trainees by country and provides contact information. We are at a transition time regarding research ethics scholarship and practice in Africa: ten years ago there were a handful of African professionals with expertise in this area. Now there are dozens more. It is our hope that this database will provide linkage for colleagues to exchange ideas and materials and create opportunities for collaboration. Moreover, as Director of this program, I often receive requests from outsiders looking for trainees in their local region who could provide training or ethics consultation for a particular research project. It is our hope that the database will facilitate this.

The importance of professional networking cannot be overestimated. Individuals who have been working within bioethics for decades still gather new ideas from discussions with colleagues, and find new opportunities for collaborations. In March 2005, alumni and faculty of the JHU-Fogarty African Bioethics program will gather for a reunion meeting in Blantyre, Malawi. This reunion meeting will be held as a satellite meeting to precede the 6th Global Forum on Bioethics and Research. Global Forum meetings are held annually expressly to bring together colleagues working on the ethics of international research. Arguably, the most critical part of the meeting is allowing individuals to find colleagues with whom to exchange ideas and with whom to develop collaborative relationships. In the next issue of *The Bioethics Exchange*, we will report on the reunion of our alumni and the 6th GFBR meeting in Malawi. Enjoy this 2nd issue, and keep the networking going!

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REPORTS FROM THE FIELD

Establishment of a National Health Research Ethics Committee in Zambia

The Zambian health care system has been undergoing health reform since 1996. The vision of the Zambian health reform process was to provide Zambians with equity of access to high quality, cost-effective health care as close to the family as possible. With the restructuring of the Ministry of Health came the creation of an independent implementation agency for the Ministry, the Central Board of Health (CBoH). The CBoH, headed by a Director General, runs its health care delivery functions in the country through four directorates: Public Health and Research; Technical Support Services; Clinical Care and Diagnostic Services, and Health Services Planning and Management.

The CBoH's concern for research ethics has been sparked by some unfortunate ethical issues that have been witnessed in Zambia and the rise in miscommunications that occur during recruitment for research studies. It is committed to restoring the integrity of health related research studies by ensuring that the studies provide useful knowledge that will improve human welfare.

It was therefore, encouraging when the Minister of Health reiterated these facts during his official address to the third National Health Research Conference held at the Mulungushi International Conference Centre in Lusaka from 20th to 22nd January 2005. During his address, he stressed that health research should be guided by two fundamental moral commitments. These are sustainable improvement in human welfare through expansion of frontiers of scientific knowledge and understanding of disease patterns and changing human conditions; and protection of the dignity and health interests of participants as subjects of research programs. In recognition of this, the Ministry planned to establish a National Health Research Ethics Committee (NHREC). It is expected that once this committee is in place, the many challenges related to regulation, coordination and monitoring of research ethics in Zambia will be a thing of the past.

The Minister of Health recognized the fact that although there were already in existence two Ethics Review Committees under the University of Zambia and the Tropical Diseases Research Centre, they operated under guidelines and standard operating procedures of their respective institutional authorities and therefore, could not be designated as national research ethics committees. The lack of a national research ethics committee meant that some health research work does not

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AMANET/NIH First Advanced Course on Ethics in Biomedical Research that Involves Human Subjects

Increasing involvement of human subjects in research keep revealing new ethical dilemmas, in addition, investigators in health research ethics and similar endeavors keep revealing new ethical concerns. To make certain that there is no exploitation of human subjects, current and future research practices need be subjected to even closer scrutiny, especially in developing countries where regulatory systems are still weak, and sometimes nonexistent.

In recognition of this, The African Malaria Network Trust (AMANET), in collaboration with the Department of Clinical Bioethics of the US National Institutes of Health, and the National Institute of Allergy and Infectious Diseases, organized an *Advanced Course on Ethics in Biomedical Research that Involves Human Subjects*. The three-day training workshop was held from 1-3 December 2004, in Zanzibar, Tanzania, attracting 50 researchers and ethicists from Cameroon, Egypt, Sudan, Uganda, Kenya, Tanzania, Malawi, Zambia, Zimbabwe and South Africa.

The main objective of the course was to provide researchers with advanced training on current and emerging ethical issues involved in the planning, implementation and dissemination of biomedical research and findings.

The training covered such topics as informed consent (new issues), decisional incapacity, gradations of ancillary-care, the ethical perspective of Data Safety Monitoring Boards, handling and

exchange of stored tissues, reasonable availability and fair benefits, the ethics of traditional medicine, coercion and undue inducement in clinical research, and a quick perusal of ethical review systems of some of the participating countries.

Ethical concerns in malaria vaccine development were raised at the founding of the African Malaria Vaccine Testing Network (AMVTN) in 1995. AMVTN was succeeded by AMANET in 2003. In order to address ethical issues pertinent to research in Africa AMVTN in 1999 organized a seminar¹ whose recommendations led to the founding of PABIN, the Pan-African Bioethics Initiative, and the development of AMVTN/AMANET ethics workshops. So far AMANET has organized six such training workshops, benefiting over 200 African researchers, members of ethics review committees and associated personnel. AMANET has also organized a workshop on development of standard operating procedures for ethics review committees; another will follow soon.

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1. Rugemalila JB, Kilama WL. Proceedings Seminar on Health Research Ethics in Africa. *Acta Trop.* 2001 Jan 15; 78 Suppl 1:S1-126. [Full text available online: www.parasitology-online.com]

RESPONSE TO THE CHALLENGE

In each issue we pose an open “challenge”. As such, in Volume 1, Issue 1 of the *Bioethics Exchange* the following challenge was presented: Ethics of doing research with orphans in Africa. Does this require special protections over and above those described in international guidelines?

The article on AIDS orphans and other vulnerable children (OVC) in Africa is timely because it draws attention to a previously neglected issue. The problem that OVC faces is one of the symptoms of other more serious problems affecting many citizens living on the continent. The first is the deep-seated stigma associated with infection with HIV/AIDS. In Nigeria, for example, HIV/AIDS has been in existence in the country for about two decades now, and majority of the citizens know that HIV cannot be transmitted through casual contact. Yet, stigma and discrimination of persons living with HIV/AIDS (PLWHA) persists at all levels, and especially among all health workers, including physicians and nurses. So, the neglect of the needs of OVC is an extension of the stigma associated with HIV. Secondly, many PLWHA have limited access to treatment with anti-retroviral (ARV) drugs due to poverty. As experience from many developed countries show, adequate access to treatment with ARV drugs has enabled many PLWHA to lead productive lives. By contrast, the current situation in many African countries is that

AIDS saps the financial resources of PLWHA as well as those of their relatives and families such that when the PLWHA dies, the family is so impoverished that there is virtually nothing left to take care of children left behind. To address the root causes of problems of OVC we must prevent situations which create OVC in the first place. This would require that we intensify prevention activities to avoid new infections and improve access to treatment for those already infected.

1. There can and should be equity and effectiveness in addressing the needs of OVC.
2. Communities and other care providers need to accept that OVC are first and foremost human beings and are therefore entitled to fundamental rights. The problem is that OVC cannot advocate for these rights themselves and we all owe it to them to do so.
3. Health workers can become effective community orphan workers but they would require initial and continuing education to perform this role.
4. The use of Management Information Systems is appropriate because it helps not only to define the nature and extent of problems of OVC but can also be a valuable tool in measuring progress in dealing with OVC-related problems.

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TRAINEE SPOTLIGHT: BAVON MUPENDA

I was born in Kalambo in the Democratic Republic of the Congo, in 1960. My father, Mr. Léon Ibonga, was a Chief Mason, and my mother, Mrs Adèle Sakina, a housewife. I started my primary school in Kalima, after which I joined a seminary for my secondary school as I had a dream of becoming a Catholic Priest. Eventually though, I joined the Ecole d'Application du Collège Kalumbwa in Shabunda, where I majored in Education completing my secondary studies in 1980.

I was then selected as a teacher at the Collège Kalumbwa, where I taught for three years, after which I joined the Université de Lubumbashi for a three year degree program in Sociology and Anthropology. Two years after completing my undergraduate studies, I finished my MA degree in sociology. I then became an assistant lecturer in several colleges in my country.



Being selected as an assistant lecturer gave me an opportunity to select areas of my interest. I started dreaming of doing either sociology or law or medical sociology. I loved research methodology and social ethics, which were among the courses I was teaching. Eventually, through a partnership created between my universities, the Université Libre des Pays des Grands Lacs and the Tropical Institute of Community Health and Development (TICH), a Kenyan institution, I was selected to do an MPH program in Community Health and Development from 2000 to 2002. The program was in English and I was from a French speaking country. Life became tough but I brilliantly finished the program while getting interested in Bioethics and Research Ethics. With the help of Dr. Dan Kaseje, I wrote a contribution to the WHO analysis of the ethical issues related to Long Term Care for people living with HIV/AIDS, while working as a visiting lecturer at TICH.

One day, Dr. Dan Kaseje gave me a form to fill out. It was an application for a fellowship program in Bioethics for African professionals at the Johns Hopkins University. I filled out the form and later on, I was happily surprised to learn that I was one of three candidates selected for the program.

My interest in research ethics developed as I participated in the seminars and courses offered at the JHU, the NIH and the Georgetown University and my participation in IRB meetings.

None of my two universities had an IRB, therefore, it was questionable for me to go back home and conduct a research without an IRB that would review my protocol. I was then advised to focus my practicum on creating an IRB in my university. If I decided to create it in Kisumu alone, my other university would have asked me to explain the reason for my choice. If I decided to open it in Goma, TICH would have realized that their helping me to go to the JHU was not taken into consideration. I decided to create two IRBs.

I have gained a great deal from my training at JHU: I took my first GRE exam. I was equipped with essential elements to be able to guide an IRB and to oversee protocols, to train students both at TICH and at ULPGL. I even had an opportunity to share my experience in creating IRB with a US based institution through a colleague. Today, there is a regular radio program to discuss issues related to research ethics, supported by regular messages sent by JHU to alumni. I have also developed a curriculum of research ethics that is being experimented for MPH students at TICH.

I went back to my universities to continue my work as lecturer but at the same time, I am the Chairperson of one IRB and continue to give my contribution in the progress of the other IRB.

My future aspiration is to pursue further studies for a PhD in Research Ethics related to Health Policy Management with a focus on Policy at national and local levels on HIV/AIDS. I would like to consider the relationship between Health professionals and researchers on one hand, and patients and research participants on the other hand. Professionally, I have always enjoyed working in training and research institutions. On the personal front, I am married to Yvonne W. Mupenda and am father of Liliane (18 years), Lionel (7 years), Evariste (5 years), and Martinet (1 year).

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Establishment of a National Ethics Committee in Zambia (continued from Page 1)

go through any ethics committee, while there is limited institutional capacity to monitor approved health research. The Ministry, he emphasized was also concerned about the inadequate inclusion of health research ethics in training schools for health providers. He therefore urged these institutions to consider inclusion of this important topic in their curricula. CBoH is currently working out the establishment modalities of the NHREC by June 2005.

The author of this article is Bornwell Sikateyo, a 2004 JHU Fogarty Fellow. He is the national focal point person for health systems research and is responsible for the National Health Research Secretariat. He is likely to remain as Secretary in the new NHREC. He is currently conducting a national survey aimed at making an assessment of the utilization of health research ethics among health research professionals actively engaged in health research in Zambia with financial support from the JHU-Fogarty African Bioethics Training Program.

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THE CHALLENGE

The challenge for the 3rd issue of the *Bioethics Exchange* is to debate the following:

What do you think about the ethics of pretending to be a research subject for a study, in order to learn how the informed consent process is actually conducted?

Send your comments to btadesse@jhsph.edu for publication in the 3rd issue of the *Bioethics Exchange*.

ANNOUNCEMENTS

Recent Publications of Interest

Barsdorf, N. W., Wassenaar, D. R. (2005). Racial differences in public perceptions of voluntariness of medical research participants in South Africa. *Social Science & Medicine*, 60 (5): 1087-1098.

Elsayed, D. E. (2004). The current situation of health research and ethics in Sudan. *Developing World Bioethics*, 4 (2): 154-159.

Tangwa, G. B. (2004). Bioethics, biotechnology, and culture: A voice from the margins. *Developing World Bioethics*, 4 (2): 125-138.

International Conferences

June 22-24, 2005. The Department of Clinical Bioethics, NIH, the NIAID, and the Emerging Infectious Disease Program are organizing a Latin America Conference on Ethical Aspects of Clinical Research in Lima, Peru. For more information contact Dr. Lie at rlie@cc.nih.gov.

November 28-29, 2005. Center of Biomedical Ethics and Culture in Pakistan, is organizing a Research Ethics Workshop. For further information contact the organizers at bioethics@siut.org.

March 17 – 20, 2005. Clinical Ethics Consultation: Second International Conference, Current state of the art and issues affecting ethics consultation. University of Basel, Switzerland www.iaeme.ch

For other meetings of interest please visit <http://www.who.int/ethics/events/date/2005/en/>

Announcements

Three annual awards for Excellence in Human Research Protection are given by the Health Improvement Institute to encourage and recognize excellence and innovation in human research protection. For more information contact the Awards Coordinator at hii@has.com.

Your comments about the current issue, and ideas for the next issue are what will keep the Bioethics Exchange an interesting and lively newsletter!!

Please send contributions and suggestions to btadesse@jhsph.edu

THE JOHNS HOPKINS UNIVERSITY-FOGARTY AFRICAN BIOETHICS TRAINING PROGRAM

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